

Clinical trial results:

A Phase 4 Open Label, Prospective Study in Patients With Pompe Disease to Evaluate the Efficacy and Safety of Alglucosidase Alfa Produced at the 4000 L Scale

Summary

EudraCT number 2015-000512-18	
Trial protocol	Outside EU/EEA
Global end of trial date	29 December 2014
Results information	
Result version number v2 (current)	
This version publication date	17 July 2016
First version publication date	25 June 2015
Version creation reason	Correction of full data set Clarification of unit of measure in endpoint analysis.
Trial information	
Trial identification	
Sponsor protocol code	AGLU09411/EFC12720
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number) NCT01526785	
WHO universal trial number (UTN) U1111-1162-8919	
Notes:	
Sponsors	
Sponsor organisation name	Genzyme Corporation
Sponsor organisation address	500 Kendall Street, Cambridge, MA, United States, 02142
Public contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.com
Notes:	
Paediatric regulatory details	
Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes
Makaas	

Notes:

Results analysis stage			
Analysis stage	Final		
Date of interim/final analysis	05 March 2015		
Is this the analysis of the primary completion data?	No		
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Global end of trial reached?	Yes		
Global end of trial date	29 December 2014		
Was the trial ended prematurely?	No		

Notes:

General information about the trial

Main objective of the trial:

The primary efficacy objective was to demonstrate comparability of treatment with alglucosidase alfa produced at the 4000L scale in subjects previously treated with 160L scale alglucosidase alfa.

Protection of trial subjects:

Pediatric Subjects: The study was conducted by investigators experienced in the treatment of pediatric subjects. The parent(s) or guardian(s) as well as the children were fully informed of all pertinent aspects of the clinical trial as well as the possibility to discontinue at any time. In addition to the consent form for the parent(s)/guardian(s), an assent form in child-appropriate language was provided and explained to the child. Repeated invasive procedures were minimized. The number of blood samples as well as the amount of blood drawn were adjusted according to age and weight. A topical anesthesia may have been used to minimize distress and discomfort.

Adult Subjects: Subjects were fully informed of all pertinent aspects of the clinical trial as well as the possibility to discontinue at any time in language and terms appropriate for the subject and considering the local culture. During the course of the trial, subjects were provided with individual subject cards indicating the nature of the trial the subject is participating, contact details and any information needed in the event of a medical emergency.

Collected personal data and human biological samples were processed in compliance with the Sanofi-Aventis Group Personal Data Protection Charter ensuring that the Group abides by the laws governing personal data protection in force in all countries in which it operates.

Background therapy: -		
Evidence for comparator: -		
Actual start date of recruitment	09 March 2012	
Long term follow-up planned	No	
Independent data monitoring committee (IDMC) involvement?	Yes	

Notes:

Population of trial subjects	
Subjects enrolled per country	
Country: Number of subjects enrolled	United States: 113
Worldwide total number of subjects	113

Worldwide total number of subjects | 113 |

EEA total number of subjects | 0 |

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	33
Children (2-11 years)	73
Adolescents (12-17 years)	6
Adults (18-64 years)	1
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study was conducted in United States. A total of 113 subjects were treated between 9 March 2012 and 4 June 2014.

Period 1

Period 1 title	Overall Study (overall period)	
Is this the baseline period?	Yes	
Allocation method	Not applicable	
Blinding used	Not blinded	

Arms

Arm title	Alglucosidase Alfa
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Arm description:

Alglucosidase alfa produced at 4000 L scale for 52 weeks.

Arm type	Experimental
Investigational medicinal product name	Alglucosidase Alfa
Investigational medicinal product code	
Other name	Lumizyme®
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

EU-CTR publication date: 17 July 2016

Dosage and administration details:

4000 L alglucosidase alfa as per subject's routine practice.

Number of subjects in period 1	Alglucosidase Alfa
Started	113
Completed	100
Not completed	13
Consent withdrawn by subject	2
Physician decision	1
Death	2
Study Terminated by Sponsor	8

Baseline characteristics

Reporting groups		
Reporting group title Alglucosidase Alfa		
Reporting group description:		
Alglucosidase alfa produced at 4000 L scale for 52 weeks.		

Reporting group values	Alglucosidase Alfa	Total	
Number of subjects	113	113	
Age categorical			
Units: Subjects			
			•
Age continuous			
Units: years			
arithmetic mean	4.8		
standard deviation	± 3.73	-	
Gender categorical			
Units: Subjects			
Female	53	53	
Male	60	60	

EU-CTR publication date: 17 July 2016

End points

End points reporting gro	oups	
Reporting group title	Alglucosidase Alfa	
Reporting group description:		
Alglucosidase alfa produced at	: 4000 L scale for 52 weeks.	

Primary: Percentage of Subjects	Who were Clinically Stable or Improved at Week 52
	Percentage of Subjects Who were Clinically Stable or Improved at Week $52^{[1]}$

End point description:

Clinical stability defined as absence of death due to disease progression or new dependency on invasive ventilation and; decline in cardiac status, motor function, and pulmonary function from baseline. Analysis was carried out on full analysis population defined as all subjects who receive at least 1 infusion of 4000 L

alglucosidase alfa during the study.

End point type	Primary

End point timeframe:

Week 52

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses for this endpoint

End point values	Alglucosidase Alfa		
Subject group type	Reporting group		
Number of subjects analysed	104		
Units: percentage of subjects			
number (confidence interval 95%)	83.7 (75.1 to 90.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Survival Rate at Week 52

End point title Survival Rate at Week 52

End point description:

Percentage of subjects who were alive at Week 52, were reported. Survival rate was calculated by Kaplan-Meier estimate. Analysis was carried out on full analysis population.

End point type Secondary

End point timeframe:

Week 52

End point <u>values</u>	Alglucosidase Alfa		

End point values	Alglucosidase Alfa		
Subject group type	Reporting group		
Number of subjects analysed	67		
Units: Z score			
arithmetic mean (standard deviation)	-0.5 (± 1.71)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline on Gross Motor Function Measure-88 (GMFM-88) at Week 52

End point title	Change From Baseline on Gross Motor Function Measure-88
	(GMFM-88) at Week 52

End point description:

GMFM-88 (88-item measure to detect gross motor function) consists of 5 components, each measured on a 4-point Likert scale. The score for each dimension was expressed as a percentage of the maximum score for that dimension. Total score ranges from 0% to 100%, where higher scores indicate better motor functions. Analysis was carried out on full analysis population. Number of subjects analysed = subjects with baseline and Week 52 GMFM-88 data.

End point type	Secondary
End point timeframe:	
Baseline, Week 52	

End point values	Alglucosidase Alfa		
Subject group type	Reporting group		
Number of subjects analysed	90		
Units: percentage of total score			
arithmetic mean (standard deviation)	3.7 (± 17.46)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Forced Vital Capacity (FVC) at Week 52- At Supine Position

End point title	Change From Baseline in Forced Vital Capacity (FVC) at Week
	52- At Supine Position

End point description:

Percent predicted FVC values are reported. FVC is the volume of air that can forcibly be blown out after full inspiration in the upright position, measured in liters. Predicted forced vital capacity is based on a

formula using sex, age, and height of a person, and is an estimate of healthy lung capacity. Percent of predicted FVC = (observed value)/(predicted value) * 100%. Analysis was carried out on full analysis population. Number of subjects analysed = subjects with baseline and Week 52 FVC data.

End point type	Secondary
End point timeframe:	
Baseline, Week 52	

End point values	Alglucosidase Alfa		
Subject group type	Reporting group		
Number of subjects analysed	13		
Units: percent predicted FVC			
arithmetic mean (standard deviation)	3.2 (± 11.07)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Forced Vital Capacity (FVC) at Week 52- At Sitting Position

End point title	Change From Baseline in Forced Vital Capacity (FVC) at Week
	52- At Sitting Position

End point description:

Percent predicted FVC values are reported. FVC is the volume of air that can forcibly be blown out after full inspiration in the upright position, measured in liters. Predicted forced vital capacity is based on a formula using sex, age, and height of a person, and is an estimate of healthy lung capacity. Percent of predicted FVC = (observed value)/(predicted value) * 100%. Analysis was carried out on full analysis population. Number of subjects analysed = subjects with baseline and Week 52 FVC data.

End point type	Secondary
End point timeframe:	
Baseline, Week 52	

End point values	Alglucosidase Alfa		
Subject group type	Reporting group		
Number of subjects analysed	22		
Units: percent predicted FVC			
arithmetic mean (standard deviation)	2.3 (± 11.8)		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

All Adverse Events (AE) were collected from signature of the informed consent form up to the final visit (Week 52) regardless of seriousness or relationship to investigational product.

Adverse event reporting additional description:

Reported adverse events are treatment-

emergent adverse events that is AEs that developed/worsened during the 'on treatment period' (from the first infusion of study drug up to 30 days after last infusion of study drug). Analysis was performed on safety population which included all treated subjects.

Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.1
Reporting groups	
Reporting group title	Alglucosidase Alfa 4000 L
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Reporting group description:

Alglucosidase alfa produced at 4000 L scale for 52 weeks.

Serious adverse events	Alglucosidase Alfa 4000 L	
Total subjects affected by serious adverse events		
subjects affected / exposed	73 / 113 (64.60%)	
number of deaths (all causes)	6	
number of deaths resulting from adverse events		
Vascular disorders		
Hypotension		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Jugular Vein Thrombosis		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Surgical and medical procedures		
Central Venous Catheterisation		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Therapeutic Procedure		

subjects affected / exposed	1 / 113 (0.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0/0		
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	2 / 113 (1.77%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Chills			
subjects affected / exposed	2 / 113 (1.77%)		
occurrences causally related to treatment / all	3 / 3		
deaths causally related to treatment / all	0 / 0		
Device Malfunction			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0/0		
Device Breakage	1		1
subjects affected / exposed	1 / 113 (0.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypothermia	İ		i i
subjects affected / exposed	1 / 113 (0.88%)		
occurrences causally related to	1		
treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oedema Peripheral			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences causally related to treatment / all	1/1		
deaths causally related to treatment / all	0 / 0		
Pyrexia	1		i i
subjects affected / exposed	10 / 113 (8.85%)		
occurrences causally related to treatment / all	4 / 16		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			

Acute Respiratory Distress Syndrome		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences causally related to treatment / all	0 / 2	
deaths causally related to treatment / all	0 / 0	
Acute Respiratory Failure		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences causally related to treatment / all	0 / 4	
deaths causally related to treatment / all	0 / 0	
Apnoea	1	
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Aspiration	1	
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Atelectasis	1	
subjects affected / exposed	3 / 113 (2.65%)	
occurrences causally related to treatment / all	0 / 5	
deaths causally related to treatment / all	0 / 0	
Bronchial Secretion Retention	i i	
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Bronchiectasis	į i	
subjects affected / exposed	2 / 113 (1.77%)	
occurrences causally related to treatment / all	0/3	
deaths causally related to treatment / all	0 / 0	
Chronic Respiratory Failure	į i	
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
1		ı
Dyspnoea	1	l l

subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatmen			
treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deat	subjects affected / exposed	5 / 113 (4.42%)	
treatment / all		0 / 5	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatmen		0 / 0	
occurrences causally related to treatment / all deaths causally related to treatment / all subjects affected / exposed occurrences causally related to treatment / all deaths causally related to tre	Cough		
treatment / all deaths causally related to treatment / all Hypoxia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to	subjects affected / exposed	2 / 113 (1.77%)	
treatment / all		0 / 2	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Pneumonia Aspiration subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Pneumothorax subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all		0 / 0	
occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 Pneumonia Aspiration subjects affected / exposed occurrences causally related to treatment / all 0 / 0 Pneumothorax subjects affected / exposed 0 / 4 / 113 (3.54%) occurrences causally related to treatment / all 0 / 0 Pneumothorax subjects affected / exposed 0 / 2 / 2 / 2 / 2 / 2 / 2 / 2 / 2 / 2 /	Нурохіа		
treatment / all deaths causally related to treatment / all Pneumonia Aspiration subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Pneumothorax subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Pulmonary Granuloma subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	subjects affected / exposed	3 / 113 (2.65%)	
Pneumonia Aspiration subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Respiratory Disorder subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all		0 / 3	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Pneumothorax subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all		0 / 0	
occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 Pneumothorax subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all 0 / 0 Pulmonary Granuloma subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all 0 / 0 Pulmonary Granuloma subjects affected / exposed 0 / 1 deaths causally related to treatment / all 0 / 0 Respiratory Disorder subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all 0 / 0 Respiratory Disorder subjects affected / exposed 0 / 1 deaths causally related to treatment / all 0 / 0 Respiratory Distress subjects affected / exposed 1 / 113 (14.16%) occurrences causally related to treatment / all 0 / 23 deaths causally related to treatment / all 0 / 22	Pneumonia Aspiration		
treatment / all deaths causally related to treatment / all Pneumothorax subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Pulmonary Granuloma subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Respiratory Disorder subjects affected / exposed occurrences causally related to treatment / all deaths causally related to	subjects affected / exposed	4 / 113 (3.54%)	
Pneumothorax subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all		0 / 4	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Pulmonary Granuloma subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Respiratory Disorder subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Respiratory Distress subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all		0 / 0	
occurrences causally related to treatment / all deaths causally related to treatment / all	Pneumothorax		
treatment / all deaths causally related to treatment / all Delimonary Granuloma subjects affected / exposed occurrences causally related to treatment / all deaths causally related to	subjects affected / exposed	1 / 113 (0.88%)	
Pulmonary Granuloma subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all		0 / 2	
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treatment / all deaths causally related to treatment / all Respiratory Disorder subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Respiratory Distress subjects affected / exposed occurrences causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all o / 23 o / 24	subjects affected / exposed	1 / 113 (0.88%)	
Respiratory Disorder subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Respiratory Distress subjects affected / exposed occurrences causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all of / 23		0 / 1	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Respiratory Distress subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all o / 2		0 / 0	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Respiratory Distress subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all o / 23 1 / 113 (0.88%) 0 / 0 1 / 113 (14.16%) 0 / 23	Respiratory Disorder		
occurrences causally related to treatment / all deaths causally related to treatment / all Respiratory Distress subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all 0 / 1 0 / 0 16 / 113 (14.16%) 0 / 23		1 / 113 (0.88%)	
deaths causally related to treatment / all 0 / 0 Respiratory Distress subjects affected / exposed 16 / 113 (14.16%) occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 2			
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to 0 / 23 occurrences causally related to 0 / 2	deaths causally related to	0 / 0	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 16 / 113 (14.16%) 0 / 23 0 / 2	Respiratory Distress		
treatment / all deaths causally related to treatment / all 0 / 2		16 / 113 (14.16%)	
deaths causally related to treatment / all 0 / 2		0 / 23	
Respiratory Failure	deaths causally related to	0 / 2	
	Respiratory Failure	İ	·

subjects affected / exposed	7 / 113 (6.19%)	
occurrences causally related to treatment / all	0 / 7	
deaths causally related to treatment / all	0 / 1	
Rhonchi		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	1 / 1	
deaths causally related to treatment / all	0 / 0	
Respiratory Tract Congestion		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Psychiatric disorders		
Mental Status Changes		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Self-Injurious Ideation		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	1 / 1	
deaths causally related to treatment / all	0 / 0	
Investigations		
Aspartate Aminotransferase Increased	1	
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Alanine Aminotransferase Increased		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Blood Albumin Decreased		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	

1	1	ı	1
Oxygen Saturation Decreased			
subjects affected / exposed	3 / 113 (2.65%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Gamma-Glutamyltransferase Increased			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0/0		
Injury, poisoning and procedural			
complications			
Feeding Tube Complication subjects affected / exposed			
	1 / 113 (0.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foreign Body			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Femur Fracture			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foreign Body Aspiration			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Traumatic Haemothorax	I		i i
subjects affected / exposed	1 / 113 (0.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tracheal Obstruction	' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' '	 	, '
subjects affected / exposed	1 / 113 (0.88%)		
occurrences causally related to	0 / 1		
treatment / all deaths causally related to	0 / 0		
treatment / all	0 / 0		I I

Bradycardia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Cardiac Arrest subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Canadia and an and		
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to	Cardiac disorders		
occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all deaths causally	1	2 / 113 /1 770//	
treatment / all deaths causally related to treatment / all Cardiac Arrest subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all			
treatment / ali Cardiac Arrest subjects affected / exposed occurrences causally related to treatment / ali deaths causally related to treatment / ali Cardiac Failure Congestive subjects affected / exposed occurrences causally related to treatment / ali deaths causally related to treatment / ali		0/2	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Cardiac Failure Congestive subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Cardio-Respiratory Arrest subjects affected / exposed occurrences causally related to treatment / all Cardio-Respiratory Arrest subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Cardiopulmonary Failure subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Cyanosis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all		0 / 0	
occurrences causally related to treatment / all deaths causally related to treatment / all 0/1 Cardiac Failure Congestive subjects affected / exposed occurrences causally related to treatment / all 0/0 Cardio-Respiratory Arrest subjects affected / exposed occurrences causally related to treatment / all deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths c	Cardiac Arrest		
treatment / all deaths causally related to treatment / all Cardiac Failure Congestive subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	subjects affected / exposed	1 / 113 (0.88%)	
treatment / all 0 / 1 Cardiac Failure Congestive subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 Cardio-Respiratory Arrest subjects affected / exposed occurrences causally related to treatment / all 0 / 1 Cardioperson for a filter subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 1 Cardiopulmonary Failure subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 Cyanosis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / al		0 / 1	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all cardio-Respiratory Arrest subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all		0 / 1	
occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatmen	Cardiac Failure Congestive		
treatment / all deaths causally related to treatment / all Cardio-Respiratory Arrest subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Cardiopulmonary Failure subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Cyanosis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Left Ventricular Hypertrophy subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	subjects affected / exposed	1 / 113 (0.88%)	
treatment / all		0 / 1	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Cyanosis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Left Ventricular Hypertrophy subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all		0/0	
occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all	Cardio-Respiratory Arrest		
treatment / all deaths causally related to treatment / all Cardiopulmonary Failure subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	subjects affected / exposed	3 / 113 (2.65%)	
treatment / all		0 / 3	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Cyanosis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Left Ventricular Hypertrophy subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all		0 / 1	
occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 Cyanosis subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all 0 / 0 Left Ventricular Hypertrophy subjects affected / exposed 2 / 113 (1.77%) occurrences causally related to treatment / all 1 / 2 deaths causally related to treatment / all 0 / 0 Mitral Valve Incompetence subjects affected / exposed 0 / 1 / 113 (0.88%) occurrences causally related to treatment / all 0 / 0 Mitral Valve Incompetence subjects affected / exposed 0 / 1 / 113 (0.88%) occurrences causally related to treatment / all 0 / 0	Cardiopulmonary Failure		
treatment / all deaths causally related to treatment / all Cyanosis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Left Ventricular Hypertrophy subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Mitral Valve Incompetence subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	subjects affected / exposed	1 / 113 (0.88%)	
treatment / all 0 / 0 Cyanosis subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all deaths causally related to treatment / all Left Ventricular Hypertrophy subjects affected / exposed 2 / 113 (1.77%) occurrences causally related to treatment / all deaths causally related to treatment / all Mitral Valve Incompetence subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 1 Mitral Valve Incompetence subjects affected / exposed 0 / 1 Occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 1	·	0 / 1	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Left Ventricular Hypertrophy subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Mitral Valve Incompetence subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all		0 / 0	
occurrences causally related to treatment / all deaths causally related to treatment / all Left Ventricular Hypertrophy subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Mitral Valve Incompetence subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all	Cyanosis		
treatment / all deaths causally related to treatment / all Left Ventricular Hypertrophy subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Mitral Valve Incompetence subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all o / 0	subjects affected / exposed	1 / 113 (0.88%)	
treatment / all 0 / 0 Left Ventricular Hypertrophy subjects affected / exposed 2 / 113 (1.77%) occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 Mitral Valve Incompetence subjects affected / exposed occurrences causally related to treatment / all 0 / 1 deaths causally related to treatment / all deaths causally related to treatment / all 0 / 0		0 / 1	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Mitral Valve Incompetence subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all o/ 0 2 / 113 (1.77%) 1 / 2 0 / 0		0/0	
occurrences causally related to treatment / all deaths causally related to treatment / all Mitral Valve Incompetence subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all occurrences causally related to treatment / all	Left Ventricular Hypertrophy		
treatment / all deaths causally related to treatment / all Mitral Valve Incompetence subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all 0 / 0	subjects affected / exposed	2 / 113 (1.77%)	
treatment / all 0 / 0 Mitral Valve Incompetence subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0		1/2	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 1 0 / 0		0/0	
occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 1 0 / 0	Mitral Valve Incompetence		
treatment / all deaths causally related to treatment / all 0 / 0	subjects affected / exposed	1 / 113 (0.88%)	
treatment / all 0 / 0		0 / 1	
Pulseless Electrical Activity		0/0	
	Pulseless Electrical Activity		

subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 2	
deaths causally related to treatment / all	0 / 0	
Sinus Tachycardia		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Supraventricular Tachycardia		
subjects affected / exposed	4 / 113 (3.54%)	
occurrences causally related to treatment / all	0 / 9	
deaths causally related to treatment / all	0 / 0	
Tachycardia		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0/3	
deaths causally related to treatment / all	0 / 0	
Nervous system disorders		
Brain Injury		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Cerebral Ischaemia		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 1	
Convulsion		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences causally related to treatment / all	0 / 2	
deaths causally related to treatment / all	0 / 0	
Gross Motor Delay		i İ
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	2/2	
deaths causally related to treatment / all	0 / 0	
Loss Of Consciousness	· 	
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subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0/0	
Presyncope		1
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0/0	
Tremor		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	1/1	
deaths causally related to treatment / all	0 / 0	
Ear and labyrinth disorders		
Motion Sickness		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Eye disorders		
Eyelid Ptosis		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0/0	
Gastrointestinal disorders		
Constipation		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences causally related to treatment / all	0 / 2	
deaths causally related to treatment / all	0 / 0	
Abdominal Pain		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences causally related to treatment / all	1 / 2	
deaths causally related to treatment / all	0 / 0	
Dental Caries		1
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	

Diarrhoea		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	1 / 1	
deaths causally related to treatment / all	0 / 0	
Dysphagia		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Gastrooesophageal Reflux Disease		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Gastrointestinal Disorder		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Intussusception		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0/1	
deaths causally related to treatment / all	0 / 0	
Nausea		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	1 / 1	
deaths causally related to treatment / all	0 / 0	
Vomiting		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences causally related to treatment / all	1/2	
deaths causally related to treatment / all	0 / 0	
Hepatobiliary disorders		
Cholecystitis Acute		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to		

ı	Purpura		
	subjects affected / exposed	1 / 113 (0.88%)	
	occurrences causally related to treatment / all	0 / 1	
	deaths causally related to treatment / all	0 / 0	
	Hyperhidrosis		

subjects affected / exposed	2 / 113 (1.77%)	
occurrences causally related to treatment / all	0 / 2	
deaths causally related to treatment / all	0 / 0	
Bacterial Tracheitis		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences causally related to treatment / all	0 / 2	
deaths causally related to treatment / all	0 / 0	
Cellulitis		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Bronchiolitis		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences causally related to treatment / all	0 / 2	
deaths causally related to treatment / all	0 / 0	
Device Related Infection	l l	
subjects affected / exposed	6 / 113 (5.31%)	
occurrences causally related to treatment / all	0 / 6	
deaths causally related to treatment / all	0 / 0	
Gastroenteritis	i İ İ	
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Gastroenteritis Viral		
subjects affected / exposed	3 / 113 (2.65%)	
occurrences causally related to treatment / all	0 / 4	
deaths causally related to treatment / all	0 / 0	
Influenza		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences causally related to treatment / all	0 / 2	
deaths causally related to treatment / all	0 / 0	

	subjects affected / exposed	1 / 113 (0.88%)	
	occurrences causally related to treatment / all	0 / 1	
	deaths causally related to treatment / all	0 / 0	
	Klebsiella Bacteraemia		
	subjects affected / exposed	1 / 113 (0.88%)	
	occurrences causally related to treatment / all	0 / 1	
	deaths causally related to treatment / all	0 / 0	
	Lobar Pneumonia		
	subjects affected / exposed	1 / 113 (0.88%)	
	occurrences causally related to treatment / all	0 / 2	
	deaths causally related to treatment / all	0 / 0	
	Lung Infection		
	subjects affected / exposed	1 / 113 (0.88%)	
	occurrences causally related to treatment / all	0 / 1	
	deaths causally related to treatment / all	0/0	
	Metapneumovirus Infection		
	subjects affected / exposed	3 / 113 (2.65%)	
	occurrences causally related to treatment / all	0 / 3	
	deaths causally related to treatment / all	0 / 0	
	Otitis Media Acute		
	subjects affected / exposed	1 / 113 (0.88%)	
	occurrences causally related to treatment / all	0 / 1	
	deaths causally related to treatment / all	0 / 0	
	Parainfluenzae Virus Infection	ĺ	
	subjects affected / exposed	1 / 113 (0.88%)	
	occurrences causally related to treatment / all	0 / 1	
	deaths causally related to treatment / all	0 / 0	
İ	Periumbilical Abscess	į	
	subjects affected / exposed	1 / 113 (0.88%)	
	occurrences causally related to treatment / all	0 / 1	
	deaths causally related to treatment / all	0 / 0	
i	Pneumonia	i i	
1		1 1	ı

subjects affected / exposed	25 / 113 (22.12%)	
occurrences causally related to treatment / all	0 / 33	
deaths causally related to treatment / all	0 / 1	
Pneumonia Parainfluenzae Viral		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Pneumonia Respiratory Syncytial Viral		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences causally related to treatment / all	0 / 2	
deaths causally related to treatment / all	0 / 0	
Pneumonia Pseudomonal		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Pneumonia Viral		
subjects affected / exposed	3 / 113 (2.65%)	
occurrences causally related to treatment / all	0 / 4	
deaths causally related to treatment / all	0 / 0	
Respiratory Syncytial Virus Bronchiolitis		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0/0	
Respiratory Syncytial Virus Infection		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Respiratory Tract Infection		
subjects affected / exposed	4 / 113 (3.54%)	
occurrences causally related to treatment / all	0 / 4	
deaths causally related to treatment / all	0 / 0	
Rhinovirus Infection		

subjects affected / exposed	3 / 113 (2.65%)	
occurrences causally related to treatment / all	0 / 4	
deaths causally related to treatment / all	0 / 0	
Respiratory Tract Infection Viral		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Sepsis		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences causally related to treatment / all	0 / 2	
deaths causally related to treatment / all	0 / 0	
Staphylococcal Infection		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Tracheitis		
subjects affected / exposed	5 / 113 (4.42%)	
occurrences causally related to treatment / all	0 / 7	
deaths causally related to treatment / all	0 / 0	
Tracheostomy Infection		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Urinary Tract Infection		
subjects affected / exposed	3 / 113 (2.65%)	
occurrences causally related to treatment / all	0 / 3	
deaths causally related to treatment / all	0 / 0	
Upper Respiratory Tract Infection		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences causally related to treatment / all	0 / 2	
deaths causally related to treatment / all	0 / 0	
Urinary Tract Infection Bacterial	į į	

subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all o/ 0 Urinary Tract Infection Staphylococcal subjects affected / exposed occurrences causally related to treatment / all o/ 0 Urosepsis subjects affected / exposed occurrences causally related to treatment / all o/ 0 Uriosepsis subjects affected / exposed occurrences causally related to treatment / all o/ 0 Viral Infection subjects affected / exposed occurrences causally related to treatment / all o/ 0 Wetablism and nutrition disorders Dehydration subjects affected / exposed occurrences causally related to treatment / all o/ 0 Metablism and nutrition disorders Dehydration subjects affected / exposed occurrences causally related to treatment / all o/ 0 Failure To Thrive subjects affected / exposed occurrences causally related to treatment / all o/ 0 Failure To Thrive subjects affected / exposed occurrences causally related to treatment / all o/ 0 Filuid Overload subjects affected / exposed occurrences causally related to treatment / all o/ 0 Filuid Overload subjects affected / exposed occurrences causally related to treatment / all o/ 0 Filuid Overload subjects affected / exposed occurrences causally related to treatment / all o/ 0 Filuid Overload subjects affected / exposed occurrences causally related to treatment / all o/ 0 Hypoglycaemia subjects affected / exposed occurrences causally related to treatment / all o/ 0 Hypoglycaemia subjects affected / exposed occurrences causally related to treatment / all o/ 0 deaths causally related to treatment / all o/ 0 Hypoglycaemia subjects affected / exposed occurrences causally related to treatment / all o/ 0 deaths causally related to treatment / all o/ 0 deaths causally related to treatment / all o/ 0 deaths causally related to treatment / all o/ 0 deaths causally related to treatment / all o/ 0 deaths causally related to treatment / all o/ 0 deaths causally related to treatment / all o/ 0 deaths causally related to treatment /			
treatment / all deaths causally related to treatment / all Jinnary Tract Infection Staphylococcal subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Jurosepsis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to	subjects affected / exposed	1 / 113 (0.88%)	
Urinary Tract Infection Staphylococcal subjects affected / exposed occurrences causally related to treatment / all deaths causally related to		0 / 1	
Staphylococcal subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Urosepsis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Viral Infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all O / 0 Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences causally related to treatment / all deaths causally related to		0 / 0	
occurrences causally related to treatment / all deaths causally related to treatment / all Urosepsis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to de			
treatment / all deaths causally related to treatment / all Urosepsis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Viral Infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to	subjects affected / exposed	1 / 113 (0.88%)	
Urosepsis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to		0 / 1	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to		0 / 0	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to	Urosensis		
treatment / all deaths causally related to treatment / all Viral Infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to		1 / 113 (0.88%)	
treatment / all		0 / 1	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all		0 / 0	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Viral Infection		
treatment / all deaths causally related to treatment / all Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to		2 / 113 (1.77%)	
Metabolism and nutrition disorders Dehydration subjects affected / exposed 3 / 113 (2.65%) occurrences causally related to treatment / all deaths causally related to treatment / all desths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to 0 / 0 Hypoglycaemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to 0 / 1 treatment / all deaths causally related to 0 / 1 treatment / all deaths causally related to 0 / 1		0 / 2	
Dehydration subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all failure To Thrive subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all fluid Overload subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to		0 / 0	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Failure To Thrive subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Fluid Overload subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to	Metabolism and nutrition disorders		
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Failure To Thrive subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Fluid Overload subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to	Dehydration		
occurrences causally related to treatment / all deaths causally related to treatment / all Failure To Thrive subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Fluid Overload subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all		3 / 113 (2.65%)	
treatment / all 0 / 0 Failure To Thrive subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 Fluid Overload subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all 0 / 1 deaths causally related to treatment / all 0 / 0 Hypoglycaemia subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all 0 / 0 Hypoglycaemia subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to		0/3	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Fluid Overload subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Hypoglycaemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to		0 / 0	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Fluid Overload subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Hypoglycaemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to	Failure To Thrive		
occurrences causally related to treatment / all deaths causally related to treatment / all Fluid Overload subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all No / 0 Hypoglycaemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to	subjects affected / exposed	1 / 113 (0.88%)	
deaths causally related to treatment / all 0 / 0 Fluid Overload subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 Hypoglycaemia subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to			
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Hypoglycaemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to		0 / 0	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Hypoglycaemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to	Fluid Overload		i i
occurrences causally related to treatment / all deaths causally related to treatment / all Hypoglycaemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to		1 / 113 (0.88%)	
deaths causally related to treatment / all 0 / 0 Hypoglycaemia subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all deaths causally related to			
subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all deaths causally related to		0 / 0	
subjects affected / exposed 1 / 113 (0.88%) occurrences causally related to treatment / all deaths causally related to			
occurrences causally related to treatment / all deaths causally related to	i	1 / 113 (0.88%)	
deaths causally related to			
	deaths causally related to	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Alglucosidase Alfa 4000 L	
Total subjects affected by non-serious adverse events		
subjects affected / exposed	113 / 113 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Cholesteatoma		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Vascular disorders		
Aortic Dilatation		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Flushing		
subjects affected / exposed	7 / 113 (6.19%)	
occurrences (all)	13	
Hypertension		
subjects affected / exposed	5 / 113 (4.42%)	
occurrences (all)	5	
Haematoma		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	3	
Pallor		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Hypotension		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Peripheral Coldness		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Surgical and medical procedures		
Central Venous Catheterisation		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	2	

Ear Tube Removal	I
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Gastrostomy Tube Removal	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	2
General disorders and administration	
site conditions	
Abasia	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Asthenia	
subjects affected / exposed	4 / 113 (3.54%)
occurrences (all)	4
Catheter Site Erythema	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
	_
Catheter Site Haemorrhage	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Catheter Site Extravasation	
subjects affected / exposed	4 / 113 (3.54%)
occurrences (all)	5
Catheter Site Inflammation	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
,	
Catheter Site Oedema	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Catheter Site Pain	
subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	3
Catheter Site Rash	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
(a)	1
Catheter Site Related Reaction	
•	-

	I	
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Catheter Site Swelling		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Chest Discomfort		
subjects affected / exposed	3 / 113 (2.65%)	
occurrences (all)	3	
Chills		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
,	2	
Chest Pain		
subjects affected / exposed	6 / 113 (5.31%)	
occurrences (all)	8	
Crepitations		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Device Breakage		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Device Dislocation		
subjects affected / exposed	4 / 113 (3.54%)	
occurrences (all)	6	
Device Issue subjects affected / exposed	1 / 112 /0 000/)	
occurrences (all)	1 / 113 (0.88%)	
occurrences (un)	1	
Device Malfunction		
subjects affected / exposed	9 / 113 (7.96%)	
occurrences (all)	21	
Device Occlusion		
subjects affected / exposed	13 / 113 (11.50%)	
occurrences (all)	15	
Discomfort		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Dicasca Progression		
Disease Progression	l	

subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Energy Increased	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Extravasation	0 (440 (4 770)
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Fatigue	
subjects affected / exposed	4 / 113 (3.54%)
occurrences (all)	4
Feeling Hot subjects affected / exposed	1 / 112 /0 000/2
	1 / 113 (0.88%)
occurrences (all)	1
Gait Disturbance	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Granuloma	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	5
Gravitational Oedema	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Influenza Like Illness	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
	_
Infusion Site Extravasation	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Infusion Site Swelling	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Injection Site Extravasation subjects affected / exposed	
	1 / 113 (0.88%)
occurrences (all)	1
Injection Site Swelling	

subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
October	
Oedema subjects affected / exposed	2 / 112 /2 650/\
occurrences (all)	3 / 113 (2.65%)
occurrences (all)	3
Malaise	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Oedema Peripheral	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Pain subjects affected / exposed	2 / 112 /2 (552)
	3 / 113 (2.65%)
occurrences (all)	3
Peripheral Swelling	
subjects affected / exposed	4 / 113 (3.54%)
occurrences (all)	5
Pyrexia	
subjects affected / exposed	61 / 113 (53.98%)
occurrences (all)	218
Secretion Discharge	
subjects affected / exposed	6 / 113 (5.31%)
occurrences (all)	9
Thirst	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Thursday In Davids	
Thrombosis In Device subjects affected / exposed	1 / 113 / 0 990/->
occurrences (all)	1 / 113 (0.88%)
occurrences (dii)	1
Immune system disorders	
Food Allergy	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Drug Hypersensitivity	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2

Hypersensitivity		
subjects affected / exposed	5 / 113 (4.42%)	
occurrences (all)	5	
Multiple Allergies		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Consequel Allegan		
Seasonal Allergy subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Reproductive system and breast disorders		
Genital Discomfort		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Vaginal Prolapse		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Vulvovaginal Disorder		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Vulvovaginal Erythema		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Vulveyaginal Pruritus		
Vulvovaginal Pruritus subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
, ,		
Respiratory, thoracic and mediastinal disorders		
Adenoidal Hypertrophy		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Aspiration		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	3	
Atelectasis		
subjects affected / exposed	5 / 113 (4.42%)	
occurrences (all)	6	
	-	
Bronchial Hyperreactivity		

subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	3 / 113 (2.05%)
()	
Bronchial Secretion Retention	
subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	6
Bronchial Wall Thickening	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Bronchomalacia subjects affected / exposed	1 (112 (2 222)
	1 / 113 (0.88%)
occurrences (all)	1
Bronchospasm	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Chaking	
Choking subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	5
Coodin ences (um)	
Cough	
subjects affected / exposed	36 / 113 (31.86%)
occurrences (all)	105
Dysphonia	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Dyspnoea subjects affected / exposed	6 (442 (5 249))
	6 / 113 (5.31%)
occurrences (all)	11
Epistaxis	
subjects affected / exposed	5 / 113 (4.42%)
occurrences (all)	5
Haemoptysis	
subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	5
• •	
Hypercapnia	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Hypoventilation	
-	I

subjects affected / exposed occurrences (all)	2 / 113 (1.77%) 2	
Hypoxia subjects affected / exposed occurrences (all)	1 / 113 (0.88%) 1	
Increased Bronchial Secretion subjects affected / exposed occurrences (all)	5 / 113 (4.42%) 5	
Increased Upper Airway Secretion subjects affected / exposed		

Pulmonary Artery Dilatation	1	
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Pulmonary Congestion		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Respiratory Disorder		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Pulmonary Hypertension		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Respiratory Distress		
subjects affected / exposed	8 / 113 (7.08%)	
occurrences (all)	10	
Respiratory Failure		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Respiratory Muscle Weakness		
subjects affected / exposed	3 / 113 (2.65%)	
occurrences (all)	3	
Respiratory Tract Congestion subjects affected / exposed	7 (112 (5 122()	
	7 / 113 (6.19%)	
occurrences (all)	8	
Respiratory Tract Haemorrhage		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	4	
Dhinitic Alloraia		
Rhinitis Allergic subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)		
occurrences (an)	2	
Rhinorrhoea		
subjects affected / exposed	24 / 113 (21.24%)	
occurrences (all)	42	
Rhonchi		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)		
occurrences (an)	2	

Sleep Apnoea Syndrome	1	1
subjects affected / exposed	4 / 113 (3.54%)	
occurrences (all)	4	
Sinus Congestion		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	3	
Sneezing		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Snoring subjects affected / exposed	1 / 112 /0 000/)	
	1 / 113 (0.88%)	
occurrences (all)	1	
Sputum Discoloured		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Courting In our		
Sputum Increased subjects affected / exposed	1 / 112 /0 000/)	
occurrences (all)	1 / 113 (0.88%)	
occurrences (an)	2	
Tachypnoea		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Throat Irritation		
subjects affected / exposed	3 / 113 (2.65%)	
occurrences (all)		
occurrences (un)	3	
Throat Tightness		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	3	
Tonsillar Hypertrophy		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2/113(1.7770)	
(***)		
Tracheal Ulcer		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Upper Respiratory Tract Congestion		
subjects affected / exposed	8 / 113 (7.08%)	
occurrences (all)	14	
		1

Upper-Airway Cough Syndrome	1 1	
subjects affected / exposed	1 / 112 (0.000/)	
	1 / 113 (0.88%)	
occurrences (all)	2	
Use Of Accessory Respiratory		
Muscles subjects affected / exposed		
	1 / 113 (0.88%)	
occurrences (all)	2	
Wheezing		
subjects affected / exposed	5 / 113 (4.42%)	
occurrences (all)	6	
Developed a discondense		
Psychiatric disorders Aggression		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)		
occurrences (aii)	2	
Agitation		
subjects affected / exposed	4 / 113 (3.54%)	
occurrences (all)	7	
Anxiety		
subjects affected / exposed	5 / 113 (4.42%)	
occurrences (all)		
occurrences (any	5	
Bruxism		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Attention Deficit/Hyperactivity		
Disorder		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Insomnia		
subjects affected / exposed	3 / 113 (2.65%)	
occurrences (all)	5	
Irritability	. , ,	
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Mental Disorder		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Mood Swings		

subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Oppositional Defiant Disorder		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Sleep Disorder		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Investigations		
Alanine Aminotransferase Abnormal		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Alanine Aminotransferase Increased		
subjects affected / exposed	3 / 113 (2.65%)	
occurrences (all)	4	
Aspartate Aminotransferase Abnormal		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Aspartate Aminotransferase Increased		
subjects affected / exposed	4 / 113 (3.54%)	
occurrences (all)	5	
Atrial Pressure Increased		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Blood Alkaline Phosphatase Increased		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Blood Creatine Phosphokinase Abnormal		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Blood Creatine Phosphokinase Mb Increased		
subjects affected / exposed	7 / 113 (6.19%)	
occurrences (all)	7	
Blood Culture Positive		

Blood Creatine Phosphokinase Increased subjects affected / exposed occurrences (all) Blood Lactate Dehydrogenase Abnormal subjects affected / exposed occurrences (all) Blood Lactate Dehydrogenase Abnormal subjects affected / exposed occurrences (all) Blood Lactate Dehydrogenase Increased subjects affected / exposed occurrences (all) Blood Potassium Decreased subjects affected / exposed occurrences (all) Blood Pressure Decreased subjects affected / exposed occurrences (all) Blood Pressure Increased subjects affected / exposed occurrences (all) Blood Pressure Systolic Increased subjects affected / exposed occurrences (all) Blood Pressure Systolic Increased subjects affected / exposed occurrences (all) Blood Uric Acid Decreased subjects affected / exposed occurrences (all) Blood Uric Acid Increased subjects affected / exposed occurrences (all) Blood Uric Acid Increased subjects affected / exposed occurrences (all) Blood Uric Acid Increased subjects affected / exposed occurrences (all) Blood Zinc Decreased subjects affected / exposed occurrences (all) Blood Zinc Decreased subjects affected / exposed occurrences (all) Blood Zinc Decreased subjects affected / exposed occurrences (all) Blood Zinc Decreased subjects affected / exposed occurrences (all)	subjects affected / exposed	1 / 113 (0.88%)	
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Blood Pressure Decreased subjects affected / exposed occurrences (all) Blood Pressure Increased subjects affected / exposed occurrences (all) Blood Pressure Increased subjects affected / exposed occurrences (all) Blood Pressure Systolic Increased subjects affected / exposed occurrences (all) Blood Uric Acid Decreased subjects affected / exposed occurrences (all) Blood Uric Acid Increased subjects affected / exposed occurrences (all) Blood Uric Acid Increased subjects affected / exposed occurrences (all) Blood Zinc Decreased subjects affected / exposed occurrences (all) Blood Zinc Decreased subjects affected / exposed occurrences (all) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%)		2 / 113 (1.77%)	
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subjects affected / exposed occurrences (all) Blood Pressure Increased subjects affected / exposed occurrences (all) Blood Pressure Systolic Increased subjects affected / exposed occurrences (all) Blood Uric Acid Decreased subjects affected / exposed occurrences (all) 1 Blood Uric Acid Increased subjects affected / exposed occurrences (all) 1 Blood Uric Acid Increased subjects affected / exposed occurrences (all) 1 Blood Zinc Decreased subjects affected / exposed occurrences (all) 1 Blood Zinc Decreased subjects affected / exposed occurrences (all) 1 1 1 1 1 1 1 1 1 1 1 1 1			
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occurrences (all) Blood Pressure Systolic Increased subjects affected / exposed occurrences (all) Blood Uric Acid Decreased subjects affected / exposed occurrences (all) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 0ccurrences (all) 1 / 113 (0.88%) 1 / 113 (0.88%) 0ccurrences (all) 1 / 113 (0.88%)	Blood Pressure Increased		
Blood Pressure Systolic Increased subjects affected / exposed occurrences (all) Blood Uric Acid Decreased subjects affected / exposed occurrences (all) Blood Uric Acid Increased subjects affected / exposed occurrences (all) Blood Uric Acid Increased subjects affected / exposed occurrences (all) Blood Zinc Decreased subjects affected / exposed occurrences (all) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%)	subjects affected / exposed	7 / 113 (6.19%)	
subjects affected / exposed occurrences (all) Blood Uric Acid Decreased subjects affected / exposed occurrences (all) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 0ccurrences (all) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%)	occurrences (all)	8	
subjects affected / exposed occurrences (all) Blood Uric Acid Decreased subjects affected / exposed occurrences (all) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 0ccurrences (all) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%)	Dieed Dressure Cycholic Incressed		
occurrences (all) Blood Uric Acid Decreased subjects affected / exposed occurrences (all) 1 Blood Uric Acid Increased subjects affected / exposed occurrences (all) 1 Blood Uric Acid Increased subjects affected / exposed occurrences (all) 1 Blood Zinc Decreased subjects affected / exposed occurrences (all) 1 1 1 1 1 1 1 1 1 1 1 1 1	·	1 / 113 (0.88%)	
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occurrences (all) Blood Uric Acid Increased subjects affected / exposed occurrences (all) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%) occurrences (all) 1 / 113 (0.88%) occurrences (all)	Blood Uric Acid Decreased		
Blood Uric Acid Increased subjects affected / exposed occurrences (all) Blood Zinc Decreased subjects affected / exposed occurrences (all) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%)		1 / 113 (0.88%)	
subjects affected / exposed occurrences (all) Blood Zinc Decreased subjects affected / exposed occurrences (all) 1 / 113 (0.88%) 1 / 113 (0.88%) 1 / 113 (0.88%)	occurrences (all)	1	
occurrences (all) Blood Zinc Decreased subjects affected / exposed occurrences (all) 1 1 1 1 1 1 1 1 1 1 1 1 1	Blood Uric Acid Increased		
Blood Zinc Decreased subjects affected / exposed occurrences (all) 1 / 113 (0.88%)	subjects affected / exposed	1 / 113 (0.88%)	
subjects affected / exposed 1 / 113 (0.88%) occurrences (all) 1	occurrences (all)	1	
subjects affected / exposed 1 / 113 (0.88%) occurrences (all) 1			
occurrences (all)		1 / 112 /0 000/	
Body Temperature Increased	occurrences (all)	1	
•	Body Temperature Increased		

subjects affected / exposed	5 / 113 (4.42%)
occurrences (all)	5
, ,	
Brain Natriuretic Peptide Increased	
subjects affected / exposed	5 / 113 (4.42%)
occurrences (all)	5
Breath Sounds Abnormal	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
	_
Creatine Urine Increased	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Creatinine Urine Increased	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	
occurrences (air)	1
Electrocardiogram Pr Shortened	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Electrocardiogram St Segment Elevation	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
	_
Electrocardiogram Qt Prolonged	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Eosinophil Count Increased	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
23342225 (4)	1
Electrocardiogram Abnormal	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Gamma-Glutamyltransferase Increased	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
	_
Haematocrit Decreased	

	_	_
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Haemoglobin Decreased		
subjects affected / exposed	3 / 113 (2.65%)	
occurrences (all)	4	
Heart Rate Increased		
subjects affected / exposed	5 / 113 (4.42%)	
occurrences (all)	5	
Liver Function Test Abnormal		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Neutrophil Count Increased		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Neutrophil Count Abnormal		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Occult Blood Positive		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Neutrophil Percentage Increased		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Ovugan Saturation Degraced		
Oxygen Saturation Decreased subjects affected / exposed	4 / 113 (3.54%)	
occurrences (all)	6	
Platelet Count Increased		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Protein Urine		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Protein Urine Present		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Pulmonary Function Test Decreased		

	1	,
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Pulse Pressure Abnormal		
subjects affected / exposed	1 / 113 (0.88%)	İ
occurrences (all)	1	
Respiratory Rate Increased		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
. ,		
Specific Gravity Urine		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Serum Ferritin Decreased		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Courtum Cultura Dacitiva		
Sputum Culture Positive subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1 / 113 (0.88%)	
(5)	1	
Staphylococcus Test Positive		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Urine Ketone Body Present		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Tuborquin Test Desitive		
Tuberculin Test Positive subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1 (0.88%)	
,		
Urine Output Decreased		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Weight Decreased		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Wainht Inger		
Weight Increased subjects affected / exposed	3 / 113 (2.65%)	
occurrences (all)	3 / 113 (2.65%)	
· · · · · · · · · · · · · · · · · · ·		
White Blood Cell Count Abnormal		

subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
White Blood Cell Count Increased subjects affected / exposed	1 / 112 /0 000/)		
	1 / 113 (0.88%)		
occurrences (all)	1		
Injury, poisoning and procedural			
complications Agitation Postoperative			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
occarrences (un)	1		
Animal Bite			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Ankle Fracture			
subjects affected / exposed	1 / 112 /0 990/ \		
	1 / 113 (0.88%)		
occurrences (all)	1		
Animal Scratch			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Arthropod Bite	_ , , , _ , _ , _ ,		
subjects affected / exposed	7 / 113 (6.19%)		
occurrences (all)	8		
Arthropod Sting			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Concussion			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Contusion			
subjects affected / exposed	6 / 113 (5.31%)		
occurrences (all)	7		
Exposure To Communicable Disease			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Eye Contusion			
Lyc Contasion	I		I

subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
,	1
Eye Injury	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Face Injury	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Fall subjects affected / exposed	11 (112 (0 720))
	11 / 113 (9.73%)
occurrences (all)	13
Feeding Tube Complication	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Femur Fracture	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
,	2
Gastrointestinal Anastomotic Leak	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	3
Foreign Body	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Gastrointestinal Stoma Complication subjects affected / exposed	1 / 112 /0 000/)
occurrences (all)	1 / 113 (0.88%)
occurrences (un)	1
Hand Fracture	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Head Injury	
subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	3
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Joint Dislocation	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Humerus Fracture	
Trainer do Fracture	

	İ
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Laryngeal Injury	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Laceration subjects affected / exposed	6 / 113 (5.31%)
occurrences (all)	6
occurrences (un)	6
Ligament Sprain	
subjects affected / exposed	5 / 113 (4.42%)
occurrences (all)	5
Limb Injury	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Lower Limb Fracture subjects affected / exposed	1 / 112 /0 000/ \
occurrences (all)	1 / 113 (0.88%)
occurrences (un)	1
Overdose	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Periorbital Haemorrhage	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Post Procedural Haemorrhage subjects affected / exposed	2 / 112 /1 770/\
occurrences (all)	2 / 113 (1.77%)
courrences (un)	2
Postoperative Respiratory Distress	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Postoperative Fever	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
5 1 18	
Procedural Nausea subjects affected / exposed	1 / 112 /0 000/ \
occurrences (all)	1 / 113 (0.88%)
occurrences (all)	1
Procedural Pain	

subjects affected / exposed	0 / 440 /7 000/3	1
	8 / 113 (7.08%)	
occurrences (all)	10	
Procedural Vomiting		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Scratch		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Skin Wound		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Skin Abrasion		
subjects affected / exposed	9 / 113 (7.96%)	
occurrences (all)	14	
0.07		
Soft Tissue Injury subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1 / 113 (0.88%)	
occurrences (un)	1	
Splinter		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	2	
Stoma Site Erythema		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Stoma Site Irritation subjects affected / exposed	2 (442 (2.65%)	
occurrences (all)	3 / 113 (2.65%)	
occurrences (an)	3	
Stoma Site Haemorrhage		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Stoma Site Reaction		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
(4)	1	
Stoma Site Rash		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Thermal Burn		
	1	1

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subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Sunburn		
subjects affected / exposed	1 / 112 /0 990/ \	
	1 / 113 (0.88%)	
occurrences (all)	1	
Tooth Avulsion		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)		
,		
Tibia Fracture		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Tooth Fracture		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Tarakh Indone		
Tooth Injury subjects affected / exposed	1 / 112 /0 000/	
	1 / 113 (0.88%)	
occurrences (all)	1	
Tracheostomy Malfunction		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Vaccination Complication		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Wound		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Waynd Dahiraana		
Wound Dehiscence	4 / 445 /5 5551	
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Congenital, familial and genetic		
disorders		
Cryptorchism		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Condition discoud.		1
Cardiac disorders	I	1

Arrhythmia		l
subjects affected / exposed	3 / 113 (2.65%)	
occurrences (all)	3	
Bundle Branch Block Right		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Bradycardia		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	4	
(4.1)	7	
Cardiac Failure		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Cardiomyopathy		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)		
occurrences (an)	1	
Diastolic Dysfunction		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Defect Conduction Intercondition		
Defect Conduction Intraventricular subjects affected / exposed	4 / 112 /2 540/	
	4 / 113 (3.54%)	
occurrences (all)	4	
Heart Valve Incompetence		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Left Ventricular Dysfunction		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Pericardial Effusion		
subjects affected / exposed	5 / 113 (4.42%)	
occurrences (all)	6	
, ,		
Right Atrial Dilatation		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Right Ventricular Hypertrophy		
subjects affected / exposed	1 / 112 (0.000/)	
	/	I
occurrences (all)	1 / 113 (0.88%)	

Sinus Tachycardia	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	3
Sinus Bradycardia subjects affected / exposed	1 / 112 /0 000/
occurrences (all)	1 / 113 (0.88%)
occurrences (aii)	2
Tachycardia	
subjects affected / exposed	13 / 113 (11.50%)
occurrences (all)	21
Cuproventricular Tachycardia	
Supraventricular Tachycardia subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	
occarrences (any	13
Wolff-Parkinson-White Syndrome	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Tricucpid Valva Incompatance	
Tricuspid Valve Incompetence subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1 113 (0.88%)
Nervous system disorders	
Allodynia	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Areflexia	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
D	
Burning Sensation subjects affected / exposed	1 / 112 /0 000/
	1 / 113 (0.88%)
occurrences (all)	1
Clumsiness	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Commission	
Convulsion subjects affected / exposed	2 / 112 /1 770/\
occurrences (all)	2 / 113 (1.77%)
occurrences (un)	2
Dizziness	

subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	3
Facial Paresis	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Formication	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Gross Motor Delay subjects affected / exposed	2 / 112 /1 770/)
occurrences (all)	2 / 113 (1.77%)
coon energy (any	2
Headache	
subjects affected / exposed	14 / 113 (12.39%)
occurrences (all)	36
Hypoaesthesia	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	2
Hyporeflexia	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Hypotonia	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Latharay	
Lethargy subjects affected / exposed	4 / 113 (3.54%)
occurrences (all)	8
Motor Developmental Delay subjects affected / exposed	1 / 112 /0 222/3
	1 / 113 (0.88%)
occurrences (all)	1
Motor Dysfunction	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Muscle Contractions Involuntary	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Nystagmus	
,	1

subjects affected / exposed	1 / 112 /0 000/
occurrences (all)	1 / 113 (0.88%)
occurrences (dii)	1
Paraesthesia	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Paralysis Flassid	
Paralysis Flaccid subjects affected / exposed	1 / 113 /0 990/\
occurrences (all)	1 / 113 (0.88%)
occurrences (any	1
Poor Quality Sleep	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Duna sur a di sa	
Presyncope subjects affected / exposed	1 / 112 /0 000/
	1 / 113 (0.88%)
occurrences (all)	1
Psychomotor Hyperactivity	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	2
Somnolence	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Speech Disorder	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
	_
Tremor	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Blood and lymphatic system disorders	
Anaemia	
subjects affected / exposed	7 / 113 (6.19%)
occurrences (all)	8
Coagulopathy	.,
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Eosinophilia	
subjects affected / exposed	6 / 113 (5.31%)
occurrences (all)	7
	<u> </u>

Iron Deficiency Anaemia	1	1	
subjects affected / exposed	2 / 113 (1.77%)		
occurrences (all)	2		
,	2		
Lymphadenitis			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Lymphadenopathy			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Neutropenia			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Cerumen Impaction			
subjects affected / exposed	3 / 113 (2.65%)		
occurrences (all)	5		
Conductive Deafness			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Geedin enees (all)			
Deafness			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Deafness Neurosensory			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Deafness Unilateral			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Ear Pain			
subjects affected / exposed	1		
	5 / 113 (4.42%)		
occurrences (all)	5 / 113 (4.42%)		
occurrences (all)			
occurrences (all) Eustachian Tube Dysfunction	8		
occurrences (all) Eustachian Tube Dysfunction subjects affected / exposed	5 / 113 (4.42%)		
occurrences (all) Eustachian Tube Dysfunction	8		

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subjects affected / exposed	5 / 113 (4.42%)
occurrences (all)	5
Otorrhoea	
subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	3
Mixed Deafness	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Tympanic Membrane Disorder	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Tympanic Membrane Perforation	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Eye disorders	
Blepharitis	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
	_
Astigmatism	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Chalazion	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
(- /	
Conjunctival Hyperaemia	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
occurrences (un)	1
Eye Discharge	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	2
Dry Eye	
subjects affected / exposed	4 / 112 /2 540/
	4 / 113 (3.54%)
occurrences (all)	5
Evo Drugitus	
Eye Pruritus	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1

Eye Irritation		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
For Constitute		
Eye Swelling subjects affected / exposed	1 / 112 /0 000/)	
occurrences (all)	1 / 113 (0.88%)	
occurrences (an)	1	
Eyelid Ptosis		
subjects affected / exposed	4 / 113 (3.54%)	
occurrences (all)	6	
Eyelid Oedema		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Hypermetropia		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Lid Sulcus Deepened		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Ocular Hyperaemia		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Myopia subjects affected / exposed		
	2 / 113 (1.77%)	
occurrences (all)	2	
Photophobia		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Strabismus		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Vision Blurred		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
astrointestinal disorders	+	
Abdominal Discomfort		

subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	3
Abdominal Distension subjects affected / exposed	1 / 112 /0 000/)
occurrences (all)	1 / 113 (0.88%)
occurrences (un)	1
Abdominal Pain	
subjects affected / exposed	10 / 113 (8.85%)
occurrences (all)	17
Abnormal Faeces	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Abdominal Pain Upper	
subjects affected / exposed	11 / 113 (9.73%)
occurrences (all)	18
Anal Fissure subjects affected / exposed	1 (112 (0.000))
	1 / 113 (0.88%)
occurrences (all)	1
Aphthous Stomatitis	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	2
Constipation	
subjects affected / exposed	20 / 113 (17.70%)
occurrences (all)	23
Dontal Carios	
Dental Caries subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	3 3
Dental Discomfort	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Dysphagia	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Diarrhoea	
subjects affected / exposed	55 / 113 (48.67%)
occurrences (all)	121
Faces Inconting and	
Faecal Incontinence	1

subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
, ,	_
Faeces Discoloured	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Flatulence	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	2
Gastric Ulcer	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
	_
Frequent Bowel Movements	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	3
Gastrointestinal Disorder	
subjects affected / exposed	4 / 113 (3.54%)
occurrences (all)	10
Gastritis	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Gastrooesophageal Reflux Disease subjects affected / exposed	4 / 112 /2 549/
occurrences (all)	4 / 113 (3.54%)
occurrences (all)	4
Gingival Bleeding	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Haematochezia	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Haemorrhoids subjects affected / exposed	1 / 112 /0 000/ \
occurrences (all)	1 / 113 (0.88%)
occurrences (un)	1
Ileus	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Lip Blister	
1	I

subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Infrequent Bowel Movements	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Mouth Ulceration	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Lip Ulceration	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
	_
Nausea subjects affected / exposed	
	12 / 113 (10.62%)
occurrences (all)	20
Oral Disorder	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Rectal Fissure	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
	_
Regurgitation	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Retained Deciduous Tooth	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Retching	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Salivary Hypersecretion	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Sensitivity Of Teeth	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Toothing	
Teething	l

		1	
subjects affected / exposed	4 / 113 (3.54%)		
occurrences (all)	4		
Tongue Spasm			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Tooth Deposit			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Toothache			
subjects affected / exposed	2 / 113 (1.77%)		
occurrences (all)	2		
Tooth Impacted			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	42 / 113 (37.17%)		
occurrences (all)	112		
. 148 - 8 - 1			
epatobiliary disorders			
Hepatic Fibrosis			
subjects affected / exposed	1 / 113 (0.88%)		
occurrences (all)	1		
Cholelithiasis			
subjects affected / exposed	1 / 112 /0 000/)		
	1 / 113 (0.88%)		
occurrences (all)	2		
kin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	3 / 113 (2.65%)		
occurrences (all)	3		
occurrences (an)	3		
Alopecia			
subjects affected / exposed	2 / 113 (1.77%)		
occurrences (all)	3		
(,			
Blister			
subjects affected / exposed	1 / 113 (0.88%)		
	' ' '		
occurrences (all)	1		
occurrences (all)	1		

subjects affected / exposed occurrences (all)	1 / 113 (0.88%)	
Decubitus Ulcer subjects affected / exposed occurrences (all)	3 / 113 (2.65%)	
Dermatitis		

subjects affected / exposed occurrences (all) 2 lyperkeratosis subjects affected / exposed occurrences (all) 2 Ingrowing Nail subjects affected / exposed occurrences (all) Ingrown Hair subjects affected / exposed occurrences (all) Ingrown Hair subjects affected / exposed occurrences (all) Ingrown Hair subjects affected / exposed occurrences (all) Ingrown Hair subjects affected / exposed occurrences (all) Ingrown Hair subjects affected / exposed occurrences (all) Ingrown Hair subjects affected / exposed occurrences (all) Ingrown Hair subjects affected / exposed occurrences (all) Ingrown Hair subjects affected / exposed occurrences (all) Ingrown Hair subjects affected / exposed occurrences (all) Ingrown Hair subjects affected / exposed occurrences (all) Ingrown Hair subjects affected / exposed occurrences (all) Ingrown Hair Subjects affected / exposed occurrences (all) Ingrown H		1
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occurrences (all) 42		21 / 112 /27 420/ \
lach Enthomatous	occurrences (all)	42
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	1
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Rash Macular	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	2
Rash Pruritic	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Red Man Syndrome	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Skin Disorder subjects affected / exposed	
	2 / 113 (1.77%)
occurrences (all)	2
Seborrhoeic Dermatitis	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Older For Collection	
Skin Exfoliation subjects affected / exposed	2 / 112 /1 770/
occurrences (all)	2 / 113 (1.77%)
occurrences (an)	2
Skin Hyperpigmentation	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Ckin Irritation	
Skin Irritation subjects affected / exposed	4 / 113 (3.54%)
occurrences (all)	4/113(3.54%)
	4
Skin Lesion	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Skin Ulcer	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
. ,	
Swelling Face	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Urticaria	
Ordicaria	I

subjects affected / exposed	9 / 113 (7.96%)	
occurrences (all)	28	
Renal and urinary disorders		
Dysuria subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	3	
Cocarrences (any	3	
Haematuria		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Incontinence		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Nephrolithiasis subjects affected / exposed	1 / 110 /0 000/	
	1 / 113 (0.88%)	
occurrences (all)	2	
Pollakiuria		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Proteinuria Proteinuria		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)		
Coouriences (an)	1	
Urinary Hesitation		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Urinary Incontinence		
subjects affected / exposed	4 / 113 (3.54%)	
occurrences (all)	4	
, ,		
Urinary Retention		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	2	
Endocrine disorders		
Precocious Puberty		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Musculoskeletal and connective tissue		
disorders		

EU-CTR publication date: 17 July 2016

Arthralgia	1	I
subjects affected / exposed	5 / 113 (4.42%)	
occurrences (all)	7	
, ,	,	
Arthropathy		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Back Pain		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	6	
Axillary Mass		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Foot Deformity		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Deformity Thorax		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Fracture Pain		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
5.6		
Hip Deformity subjects affected / exposed	1 / 112 /0 000/	
	1 / 113 (0.88%)	
occurrences (all)	1	
Joint Contracture		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	3	
Jaiot Cliffo		
Joint Stiffness subjects affected / exposed	1 / 112 /0 000/)	
	1 / 113 (0.88%)	
occurrences (all)	1	
Joint Swelling		
subjects affected / exposed	3 / 113 (2.65%)	
occurrences (all)	3	
IC mb a sis		
Kyphosis subjects affected / exposed	2 / 113 (1.77%)	
5451CCC5 411CCCC4 / CADU3C4	1 // 11 < /1 / / //6 \	I
occurrences (all)	2 / 113 (1.77 %)	

Limb Discomfort	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Muscle Contracture	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Muscle Spasms	
subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	3
Muscle Tightness	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
	_
Muscular Weakness	
subjects affected / exposed	12 / 113 (10.62%)
occurrences (all)	15
Musculoskeletal Pain	
subjects affected / exposed	4 / 113 (3.54%)
occurrences (all)	5
333333333 (4.11))
Musculoskeletal Chest Pain	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Managed and a Court	
Musculoskeletal Stiffness subjects affected / exposed	1 / 112 /0 000/)
	1 / 113 (0.88%)
occurrences (all)	1
Myalgia	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Myopathy subjects affected / exposed	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Neck Pain	
subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	5
、 ,	
Osteopenia	
subjects affected / exposed	4 / 113 (3.54%)
occurrences (all)	4

Pain In Jaw	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	3
, ,	
Pain In Extremity	
subjects affected / exposed	16 / 113 (14.16%)
occurrences (all)	23
Casliania	
Scoliosis subjects affected / exposed	(/ 112 /F 210/)
	6 / 113 (5.31%)
occurrences (all)	6
Tendinous Contracture	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
	2
Tendon Discomfort	
subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	3
Tendon Disorder	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Infections and infestations	
Abscess Limb	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
	_
Acarodermatitis	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Adamasima Tarifa attara	
Adenovirus Infection subjects affected / exposed	1 / 112 / 2 222/3
	1 / 113 (0.88%)
occurrences (all)	1
Atypical Pneumonia	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
,	
Bacterial Tracheitis	
subjects affected / exposed	5 / 113 (4.42%)
occurrences (all)	7
Beta Haemolytic Streptococcal Infection	
I Intection	I

subjects affected / exposed occurrences (all) Bronchitis subjects affected / exposed occurrences (all) Chronic Sinusitis subjects affected / exposed occurrences (all) Cellulitis subjects affected / exposed occurrences (all) Cocurrences (all) Cocurrences (all) Cocurrences (all) Cocurrences (all) Conjunctivitis subjects affected / exposed occurrences (all) Cocurrences (all)		I	ı
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occurrences (all) Cellulitis subjects affected / exposed occurrences (all) Clostridium Difficile Colitis subjects affected / exposed occurrences (all) Conjunctivitis subjects affected / exposed occurrences (all) Croup Infectious subjects affected / exposed occurrences (all) Car Infection subjects affected / exposed occurrences (all) Conjunctivitis subjects affected / exposed occurrences (all) Croup Infectious subjects affected / exposed occurrences (all) Conjunctivitis subjects affected / exposed occurrences (all) 2 / 113 (1.77%) 2 / 113 (1.77%) 2 / 113 (1.77%) 1 / 113 (10.62%) 1 / 113 (0.88%) occurrences (all) Conjunctivitis subjects affected / exposed occurrences (all) 1 / 113 (0.88%) occurrences (all)	Chronic Sinusitis		
Cellulitis subjects affected / exposed occurrences (all) Clostridium Difficile Colitis subjects affected / exposed occurrences (all) Conjunctivitis subjects affected / exposed occurrences (all) Croup Infectious subjects affected / exposed occurrences (all) Croup Infectious subjects affected / exposed occurrences (all) Car Infection subjects affected / exposed occurrences (all) Covice Related Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (0.88%) 2 / 113 (1.77%) 2 / 113 (10.62%) 2 / 113 (10.62%) 1 / 113 (0.88%) 0 / 1 / 113 (0.88%) 0 / 1 / 113 (0.88%)	subjects affected / exposed	1 / 113 (0.88%)	
subjects affected / exposed occurrences (all) Clostridium Difficile Colitis subjects affected / exposed occurrences (all) Conjunctivitis subjects affected / exposed occurrences (all) Croup Infectious subjects affected / exposed occurrences (all) Ear Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (0.88%) 2 / 113 (1.77%) 2 2 / 113 (1.77%) 2 2 / 113 (1.77%) 2 1 / 113 (0.88%) 1 / 113 (0.88%) 0 occurrences (all) 1 / 113 (0.88%)	occurrences (all)	2	
subjects affected / exposed occurrences (all) Clostridium Difficile Colitis subjects affected / exposed occurrences (all) Conjunctivitis subjects affected / exposed occurrences (all) Croup Infectious subjects affected / exposed occurrences (all) Ear Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (0.88%) 2 / 113 (1.77%) 2 2 / 113 (1.77%) 2 2 / 113 (1.77%) 2 1 / 113 (0.88%) 1 / 113 (0.88%) 0 occurrences (all) 1 / 113 (0.88%)	Cellulitis		
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Clostridium Difficile Colitis subjects affected / exposed occurrences (all) Conjunctivitis subjects affected / exposed occurrences (all) Croup Infectious subjects affected / exposed occurrences (all) Car Infection subjects affected / exposed occurrences (all) Cocurrences (all)	occurrences (all)		
subjects affected / exposed occurrences (all) Conjunctivitis subjects affected / exposed occurrences (all) Croup Infectious subjects affected / exposed occurrences (all) Ear Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (0.88%) occurrences (all)			
occurrences (all) Conjunctivitis subjects affected / exposed occurrences (all) Croup Infectious subjects affected / exposed occurrences (all) Ear Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (0.88%) occurrences (all)	Clostridium Difficile Colitis		
Conjunctivitis subjects affected / exposed occurrences (all) Croup Infectious subjects affected / exposed occurrences (all) Ear Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (6.19%) 2 / 113 (1.77%) 2 12 / 113 (10.62%) 20 12 / 113 (10.62%) 20 1 / 113 (0.88%) 1		2 / 113 (1.77%)	
subjects affected / exposed occurrences (all) Croup Infectious subjects affected / exposed occurrences (all) Ear Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (6.19%) 2 / 113 (1.77%) 2 / 113 (occurrences (all)	3	
subjects affected / exposed occurrences (all) Croup Infectious subjects affected / exposed occurrences (all) Ear Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (6.19%) 2 / 113 (1.77%) 2 / 113 (Conjunctivitis		
occurrences (all) Croup Infectious subjects affected / exposed occurrences (all) Ear Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (0.88%) occurrences (all)	=	7 / 113 (6.19%)	
subjects affected / exposed occurrences (all) Ear Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (0.88%) occurrences (all)	occurrences (all)		
subjects affected / exposed occurrences (all) Ear Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (0.88%) occurrences (all)			
occurrences (all) Ear Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (0.88%) occurrences (all)	•	2 / 442 /4 ====:	
Ear Infection subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (0.88%) occurrences (all)			
subjects affected / exposed occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 12 / 113 (10.62%) 20 1 / 113 (0.88%) 1 / 113 (0.88%)	occurrences (all)	2	
occurrences (all) Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (0.88%)	Ear Infection		
Device Related Infection subjects affected / exposed occurrences (all) 1 / 113 (0.88%)	subjects affected / exposed	12 / 113 (10.62%)	
subjects affected / exposed 1 / 113 (0.88%) occurrences (all)	occurrences (all)	20	
subjects affected / exposed 1 / 113 (0.88%) occurrences (all)	During Balata I.T. C. 11		
occurrences (all)		1 / 112 /0 000/)	
Enterovirus Infection	occurrences (all)	1	
incerovirus infection	Enterovirus Infection		

subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
	_
Ear Lobe Infection subjects affected / exposed	1 / 112 /2 222
	1 / 113 (0.88%)
occurrences (all)	1
Escherichia Urinary Tract Infection	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Erythema Infectiosum	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
	_
Folliculitis subjects affected / exposed	
	1 / 113 (0.88%)
occurrences (all)	1
Eye Infection	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2
Fungal Infection	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	2 / 113 (1.77 %)
(2
Fungal Skin Infection	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Furuncle	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Cashusanharibia	
Gastroenteritis subjects affected / exposed	11 / 113 (9.73%)
occurrences (all)	15
occurrences (an)	15
Gastroenteritis Viral	
subjects affected / exposed	4 / 113 (3.54%)
occurrences (all)	4
Gastroenteritis Norovirus	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Gastrointestinal Infection	l

subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	2
(u.,)	2
Gingival Abscess	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Gingivitis	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Haemophilus Infection	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Hand-Foot-And-Mouth Disease	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Herpes Zoster subjects affected / exposed	1 / 112 /0 000/)
	1 / 113 (0.88%)
occurrences (all)	1
Hordeolum	
subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	5
Impetigo	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
,	1
Infection	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Influenza	
subjects affected / exposed	8 / 113 (7.08%)
occurrences (all)	10
Labyrinthitis	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Lice Infestation	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Labor Brasson in	
Lobar Pneumonia	l

subjects affected / expected	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Lip Infection	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	2
Nail Infection	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Nasopharyngitis	
subjects affected / exposed	12 / 113 (10.62%)
occurrences (all)	23
Oral Candidiasis	
subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	4
Oral Herpes	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
coon choos (any	
Otitis Externa Fungal	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Otitis Externa	
subjects affected / exposed	2 / 113 (1.77%)
occurrences (all)	5
occurrences (un)	5
Otitis Media	
subjects affected / exposed	23 / 113 (20.35%)
occurrences (all)	35
Otitic Media Asuto	
Otitis Media Acute subjects affected / exposed	6 / 113 (5.31%)
occurrences (all)	7
Otitis Media Chronic	
subjects affected / exposed	3 / 113 (2.65%)
occurrences (all)	6
-1	
Pharyngitis subjects affected / exposed	7 / 440 /6 / 200
	7 / 113 (6.19%)
occurrences (all)	14
Pharyngitis Streptococcal	
Pharyngitis Streptococcal	

13 / 113 (11.50%)
24
24
17 / 113 (15.04%)
32
1 / 113 (0.88%)
1
4 / 113 (3.54%)
5
1 / 113 (0.88%)
2
5 / 113 (4.42%)
5
3 / 113 (2.65%)
3
6 / 112 / 5 210/)
6 / 113 (5.31%)
8
3 / 113 (2.65%)
4
1 / 113 (0.88%)
1
E / 113 /4 430/
5 / 113 (4.42%)
6
1 / 113 (0.88%)
2

subjects affected / exposed	3 / 113 (2.65%)	
occurrences (all)	5	
Stoma Site Infection		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Streptococcal Infection		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	3	
,	J	
Streptococcal Urinary Tract Infection		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Cub subsussaus Absassa		
Subcutaneous Abscess subjects affected / exposed	1 / 112 /0 000/)	
	1 / 113 (0.88%)	
occurrences (all)	2	
Tinea Infection		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
Tooth Abscess		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	3	
Tonsillitis		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
coom choos (an)	2	
Tracheitis		
subjects affected / exposed	7 / 113 (6.19%)	
occurrences (all)	12	
Tackh Infaction		
Tooth Infection subjects affected / exposed	1 / 112 /0 000/ \	
	1 / 113 (0.88%)	
occurrences (all)	1	

Bacterial	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	2
Upper Respiratory Tract Infection	
subjects affected / exposed	49 / 113 (43.36%)
occurrences (all)	104
Urinary Tract Infection	
subjects affected / exposed	19 / 113 (16.81%)
occurrences (all)	31
Viral Infection	
subjects affected / exposed	15 / 113 (13.27%)
occurrences (all)	23
Wash David	
Viral Rash subjects affected / exposed	2 / 112 /1 770/\
occurrences (all)	2 / 113 (1.77%)
occurrences (all)	2
Viral Upper Respiratory Tract	
Infection subjects affected / exposed	5 / 113 (4.42%)
occurrences (all)	7
(3)	/
Vulvovaginal Mycotic Infection	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Metabolism and nutrition disorders	
Abnormal Weight Gain	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Decreased Appetite	
subjects affected / exposed	4 / 113 (3.54%)
occurrences (all)	4
, ,	· ·
Dehydration	
subjects affected / exposed	5 / 113 (4.42%)
occurrences (all)	7
Electrolyte Imbalance	
subjects affected / exposed	1 / 113 (0.88%)
occurrences (all)	1
Failure To Thrive	

subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Hypochloraemia		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Hypoalbuminaemia		
subjects affected / exposed	1 / 113 (0.88%)	
occurrences (all)	1	
Hypoglycaemia		
subjects affected / exposed	3 / 113 (2.65%)	
occurrences (all)	3	
Iron Deficiency		
subjects affected / exposed	1 / 112 /0 000/)	
	1 / 113 (0.88%)	
occurrences (all)	1	
Hypokalaemia		
subjects affected / exposed	2 / 113 (1.77%)	
occurrences (all)	2	
	_	
Vitamin D Deficiency		
subjects affected / exposed	4 / 113 (3.54%)	
occurrences (all)	4	

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 October 2012	6-month administrative analysis was addedFor the primary efficacy endpoint, in addition to the analysis using the full analysis set specified in the original protocol, the analysis was also to be conducted on the Per-Protocol Analysis SetThe efficacy endpoint of left ventricular mass index Z- score (LVMI-Z) was revised to LVM-ZShortening of the post-infusion observation period was changed from being allowed after a 6-month treatment period to being allowed after a 3-month treatment periodHome infusions were changed from being allowed after 4 infusions in subjects with no history of moderate or severe infusion-associated reactions (IARs) or serious adverse events (SAEs) to being allowed after 2 infusions in subjects with no history of moderate or severe IARs or SAEsThe Sponsor's department name, Global Patient Safety and Risk Management, was updated for a recent name change to Global Pharmacovigilance and EpidemiologyText was added to clarify that pulmonary function tests were not required in young subjects unable to undergo testingThe protocol was modified to ensure that subject position during measurement of vital signs was to be recorded in the electronic case report form and that vital signs and weight were to be obtained at every study visitThe IgG antibodies, inhibitory antibodies, and urine pregnancy testing schedules were clarifiedText referring to subjects' previous treatment "in the commercial setting" was deleted as subjects treated with 160L scale product in other clinical trials were eligible to enroll Measurement of R voltage V6 and S voltage V1 were removed from the ECGText was deleted to reflect that efficacy and safety results would not be summarized by baseline Pompe disease status The presentation of results of planned clinical laboratory assessments was clarifiedThe stipulation that the Data Safety Monitoring Board (DSMB) would be comprised of 4 physicians was removed.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported